BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,336	04/18/1997	PAMELA R. CONTAG	8678-004-999	7227

23419 7590 10/22/2003

COOLEY GODWARD, LLP
3000 EL CAMINO REAL
5 PALO ALTO SQUARE
PALO ALTO, CA 94306

EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	29

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application N .	Applicant(s)	
	08/844,336	CONTAG ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *10-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed on 11-6-2000 is acknowledged. Claims 1-27 are pending. This application contains claims 10-20 to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-9 and 21-27 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 21 and 25-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

The rejection of claims 21 and 25 under 35 U.S.C. 103(a) as being unpatentable over Karube et al. in light of Sleight et al. in view of Garcia Vescovi et al. is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained and New Grounds of Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 21-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 16-17 of U.S. Patent No. 6,638,752 for the reasons set forth in the provisional rejection made in the previous Office action over U.S. Application 09/183,566. Said rejection is no longer provision since Application 09/183,566 has since issued as U.S. Patent 6,638,752.

Applicant has acknowledged the aforementioned rejection and has indicated response to said rejection will be held in abeyance until there is allowable subject matter in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The claim(s) still contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues:

1. The specification discloses that the biodetector entity is a living cell that is genetically engineered to comprise all the required components and that "the entity sheltering is a genetically engineered bacterial cell..." (see page 13, lines 24-28).

Applicant's arguments have been fully considered and deemed non-persuasive. The instant specification satisfies the written description requirement only with regards to genetically engineered bacteria that function as biodetectors. The rejected claim is drawn to bacteria that "shelter" the biodetectors i.e. the biodetectors are genetically engineered bacteria that are "sheltered" within other bacteria. The specification does not address these limitations nor would of skill in the art be able to contemplate (based on the specification) which genetically engineered bacteria would be able to function intracellularly (intrabacterially). The portions of the specification cited by Applicant support this. The specification discloses on page 13, lines 30-35, that "the biodetector entity is a living cell which is genetically engineered to comprise all the required components" and that said living cells can be bacteria (prokaryotes). Hence, a biodetector (as it applies to claim 22) is defined by the specification as genetically modified bacteria and therefore claim 22 reads on a genetically engineered bacterium within another bacteria. This embodiment, contrary to Applicant's assertion, does not meet the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-9, 22-23 and 27 under 35 U.S.C. 102(b) as being anticipated by Karube et al. in light of Sleight et al. is maintained for reasons of record.

Applicant argues:

1. The examiner has acknowledged that the reference of Karube et al. does not teach all the elements of the claim.

2. To anticipate a claim, a single source must contain of the elements of the claim.

3. The examiner uses the teachings of Sleight et al. to make up for the deficiencies of Karube et al.

Applicant's arguments have been fully considered and deemed non-persuasive. As stated previously, Sleight et al. was not used as a secondary reference but was used to illustrate that every element of the claimed invention is disclosed by Karube et al. (i.e. Sleight et al. was used to illustrate the state of the art). Karube et al. teach biosensor cells used for the detection and analysis of specific substrates. Said biosensors comprise a microorganism-sensing element that recognizes specific substrates and a transducer to convert the biochemical produced into an electronic signal (see page 54, first column). Karube et al. further teach that said transducer can be a photodetector, potentiometric electrodes, amperometric electrodes (see page 54, second column) and that said reaction can be made visible (via luminescence) by fusion of the luxAB gene to the fixAb gene (see page 56, column 1). Sleight et al. teaches the processes and components involved in signal transduction and illustrates that biodetector disclosed by Karube et al. inherently possess the properties not explicitly disclosed since the processes utilized by said

biodetectors are the same as those of the instant invention. Therefore, in absence of evidence to the contrary, Karube et al. anticipates all the limitations of the instant invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CEN

Robert A. Zeman
October 20, 2003